REMARKS

Claims 2-6, 8, 9, 11, 13, 14, 16-19, 21, 22, 24, 31-33, 35, 36 and 73-79 remain in this application. Claims 2-6, 8, 9, 11, 13, 14, 16-19, 21, 22, 24, 31, and 73-79 have been amended as method claims, namely "A method of administering an active ingredient, said method comprising chewing an oral dosage form comprising a texture masked particle." Support for such amendment can be found throughout the specification, including page 1, line 34-36, page 3, lines 5-9, page 8, lines 7-9, and Example 4. Accordingly, no issues of new matter are believed to be raised by the above amendments to the claims.

Rejections Under 35 USC 103

Claims 2, 4-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31, 33, 35-36, and 73-79 were rejected under 35 USC 103(a) as being unpatentable over CA 2,068,366 in view of Guley et al. (US 4,309,405), Roche (US 5,075,114), Kanai et al. (US 4,868,183) and Uchida et al. (US 5,215,999) and Yang et al. (US 5,576,022). See Pages 2-10 of the Office Action. According to the Office Action,

> "CA 2,068,366 teaches a taste-masked free-flowing powder including microcapsules having a particle size of 300 pm or less that includes a core element including at least one pharmaceutically active ingredient; a substantially smooth and continuous microcapsule coating on the core element formed from a coating composition including a water insoluble polymer (page 3, lines 1-11). . . . CA 2,068,366 does not teach the second coating layer is comprised of a water soluble and/or water swellable film forming polymer and an anti-grit agent such as polyethylene oxide or polyethylene glycol, the claimed ratios, or that the non-enteric polymer is hydroxypropyl cellulose. It is for this reason Kanai et al., Uchida et al., and Guley et al. are added as secondary references. . . . Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference." See Pages 2-10 of the Office Action.

As previously argued by the Applicants, while Kanai et al. may disclose a tablet coated with HPMC and polyethylene glycol (col. 39, lines 1-27), it does not disclose particles coated with such ingredients. The mere coating of tablets will not provide the anti-grit benefit to the underlining particles when the tablet is chewed as the tablet coating is broken upon chewing.

Merely coating the outside of the tablets would not remove the gritty, sandy texture of the resulting particles after the tablet is chewed and the outside tablet coating is broken. There is no disclosure, or even suggestion, that such a coating can be used for particles, let alone particles that already have a first coating as set forth in the pending claims. Furthermore, the tablet disclosed in Kanai et al. is a swallowable tablet, in which one of ordinary skill in the art would not look to for a texture masking coating (e.g., like with a chewable dosage form).

Similarly, Uchida et al. also only discloses the coating of tablets with HPMC and polyethylene glycol (col. 64, lines 1-19), not the coating of particles. As discussed above, the mere coating of tablets will not provide the anti-grit benefit to the underlining particles when the tablet is chewed as the tablet coating is broken upon chewing. Merely coating the outside of the tablets would not remove the gritty, sandy texture of the resulting particles after the tablet is chewed and the outside tablet coating is broken. There is no disclosure, or even suggestion, that such a coating can be used for particles, let alone particles that already have a first coating as set forth in the pending claims. Furthermore, as with Kanai et al., the tablet disclosed in Uchida et al. is a swallowable tablet, in which one of ordinary skill in the art would not look to for a texture masking coating (e.g., like with a chewable dosage form).

In response to this argument, the Office Action asserts:

> "The primary reference, CA 2,068,366, teaches active ingredient particles that are coated with two layers, a water insoluble polymer and a water soluble polymer. One of ordinary skill in the art at the time the invention was made would have been motivated to use a water soluble polymer such as hydroxypropyl methylcellulose and an anti-grit agent such as polyethylene glycol as the second coating in the formulations taught by the primary references because Kanai et al. and Uchida et al. teach these ingredients are used to prepare film-coated tablets. (emphasis added)" See Page 10 of the Office Action.

This response, however, fails to address the argument the Applicant is making; namely, why would one of ordinary skill in the art when looking to coat drug particles (e.g., to reduce the grittiness of the particles when used in chewable dosage forms) would look to the coatings for swallowable tablets as in Uchida et al. and Kanai et al.? It is well established that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent come teaching, suggestion or incentive supporting the combination. See, e.g.,

ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577 (Fed. Cir. 1984). The Office Action fails to provide such motivation.

Further, in the interests of furthering this application to allowance, as discussed above, Applicants have amended the pending claims as method claims, namely "a method of administering an active ingredient, said method comprising chewing an oral dosage form comprising a texture masked particle." Neither Uchida et al. and Kanai et al., disclose nor suggest, such a method, for as discussed above, the coating disclosed therein are for swallowable tablets.

With respect to Yang et al., while the reference discloses pellets having an "overcoat coating" containing HPMC and polyethylene glycol in Formulation No. 40 on col. 14, these pellets are sustained release pellets as they have a "sustained coating" containing ethylcellulose. Such pellets are different from the particles of the pending claims wherein the coatings do not retard the dissolution of the active ingredient. As stated in Yang et al., the purpose of the overcoat is to reduce the attrition of the sustained release coating during handling. See col. 18, lines 23-24 of Yang et al. Even assuming arguendo that one would, as stated in the Previous Amendment, the ratio of HPMC to polyethylene glycol in this pellet of Yang et al. is not within the range of 80:20 to 20:80 as recited in the pending claims of the present application.

In response to this argument, the Office Action asserts on page 11 "Yang et al. was added as a secondary reference to provide evidence that the same mixtures used to coat tablets are also used to "overcoat" pellets or particles. Yang et al. teach that hydroxypropyl methyl cellulose and polyethylene glycol are used as a secondary reference of particles. Therefore, it would have been obvious to the skilled artisan to try the same coating used to coat tablets to coat particles."

As discussed above, the pending claims are method claims, namely "a method of administering an active ingredient, said method comprising chewing an oral dosage form comprising a texture masked particle." Yang et al. also fails to disclose or suggest such a method, for Yang et al. fails to disclose, or suggest, chewable dosage forms.

With respect to Guley et al., the Office Action asserts "Guley et al. teach sustained release compositions comprising a core containing a drug, a seal coating surrounding the core, and a sugar coating surrounding the seal core. . . .Guley et al. teach the seal coating is selected from film forming materials which is capable of substantially protecting the core during its passage from the stomach to the intestine." See Page 5 of the Office Action. As with Kanai et

al. and Uchida et al. discussed above, Guley also discloses a coated tablet, and fails to disclose, or suggest, coated particles. Further, as noted above, the two coating of Guley et al. are also different from the first coating layer and the second coating layer of the pending claims (e.g., the second coating of Guley et al is a sugar coating and fails to disclose an anti-grit agent selected from the group consisting of polyethylene oxide, polyethylene glycol, and mixtures thereof). Still further, as with Kanai et al. and Uchida et al., the tablet disclosed in Guley et al. is a swallowable tablet, in which one of ordinary skill in the art would not look to for a texture masking coating (e.g., like with a chewable dosage form).

With respect to Roche, the Office Action asserts "Roche teaches a medicament coating comprising a blend of cellulose acetate and hydroxypropyl cellulose. The coating provides excellent taste masking while still permitting acceptable bioavailability of the active ingredient (col. 2, lines 20-28)." See Page 6 of the Office Action. While Roche discloses a coating solution comprising cellulose acetate and hydroxypropyl cellulose, like CA 2,068,366, it also fails to disclose, or suggest, the second coating layer of the pending claims.

In response to these arguments, the Office Action asserts "Guley et al. and Roche et al. were added as secondary references to provide a motivation to use a non-enteric polymer, such as hydroxypropyl cellulose in the formulation." See page 11 of the Office Action. As discussed above, the pending claims are method claims, namely "a method of administering an active ingredient, said method comprising chewing an oral dosage form comprising a texture masked particle." Both Roche and Guley et al., alone or in combination, fail to disclose or suggest such a method, for these references fail to disclose, or suggest, chewable dosage forms.

Thus, in conclusion, none of the five cited references, alone or in combination, disclose or even suggest the particles, the method of making such particles, and the dosage forms containing such particles as recited in the pending claims. Specifically, both CA 2,068,366 and Roche fails to disclose particles containing the second coating layer as recited in the pending claims. Further, one of ordinary skill in the art would not look to combine the coated particles teachings of CA 2,068,366 or Roche with either Kanai et al., Uchida et al., or Guley et al. as these references disclose tablet coatings, not particle coatings. Further, as the tablets of Kanai et al., Uchida et al., and Guley et al. are designed to be swallowed, and not chewed, one of ordinary skill in the art would not look to such references for coating solutions to texture mask particle. Further, as mentioned above, in the interests of furthering this application to allowance,

as discussed above, the pending claims are method claims, namely "a method of administering an active ingredient, said method comprising chewing an oral dosage form comprising a texture masked particle." Neither of the references, alone or in combination, disclose nor suggest, such a method.

Still further, as recited in Example 4 of the present application, the application of this second water-soluble layer were unexpectedly found to improve the resulting particles, as compared to the particles with only the taste-masking layer, when used in a chewable dosage form. As recited in Example 4, "[b]oth tablets were found to have had a similar taste, with a very slight bitterness detected by most panelists. The tablets from Example 1 [e.g., tablets made without the water-soluble layer] were found to have had a perceptible grittiness, which ranged from 'slight' to 'obvious,' and a rough surface. By contrast, the 'texture-masked' particles of the present invention produced in accordance with Example 3 were found to have had no grittiness, a smooth texture and a 'good melt-away,' i.e. the tablet was rapidly cleared from the oral cavity with minimal chewing required." Further, the use of layer was not found to retard the dissolution of the active ingredient as "100% of the acetaminophen active ingredient was released from the tablets of Example 1 and Example 3 in 45 minutes." Such an unexpected result was not taught, nor suggested, by CA 2,068,366, nor Kanai et al, Uchida et al., Yang et al., Roche, or Guley et al.

In response to such arguments, the Office Action stated "the results noted in the specification are directed to tablet formulations. Therefore, the examiner notes that the claims are not commensurate in scope with the examples provided." See page 14 of the Office Action. While the results of Example 4 were on dosage forms, such dosage forms contained coated particles which can induce gritty feel. Further, as discussed above, the pending claims are method claims, namely "a method of administering an active ingredient, said method comprising chewing an oral dosage form comprising a texture masked particle." Applicants assert that such method is commensurate with the scope of such results.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

Conclusion

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the presently presented claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/MCP0231USNP/WEM.

Respectfully submitted,

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